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UNITED STATES AIR FORCE SCHOOL OF AEROSPACE MEDICINE

EFFECTS OF ALTITUDE EXPOSURE IN PHOTOREFRACTIVE KERATECTOMY (PRK) SUBJECTS

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EFFECTS OF ALTITUDE EXPOSURE
IN
PHOTOREFRACTIVE KERATECTOMY (PRK) SUBJECTS

ABSTRACT

Purpose: To assess the effects of unpressurized altitude on visual acuity, refractive error, and corneal stability measures, pre- and post- PRK treatment. **Methods:** Sixteen male and four female subjects volunteered for altitude training and data collection. Two separate unpressurized altitude profiles were undertaken by all subjects; a 12-hour 10,000-ft (10K) and a 20-min 35,000-ft (35K) simulated altitude flights. Baseline "ground level" visual acuity, refractive error, and corneal stability data were collected prior to each profile. These measures were repeated "in-flight" at 3, 7, and 10 hours for the 10K profile and at peak altitude for the 35K profile. The test profiles were re-accomplished approximately 6 months after a subject's PRK treatment date. **Results:** No significant differences attributed to altitude exposure were found in measurements of pre- or post-PRK visual acuity, refractive error, or corneal stability, under either unpressurized altitude profile. **Conclusions:** Visual acuity, refractive error, and corneal stability data were not significantly affected by exposure to unpressurized altitude within the design of this study. Comprehensive study data results and analysis are presented.

INTRODUCTION

Although a USAF policy (August 2000) allowed Photorefractive Keratectomy (PRK) in USAF aviators, there have been few comprehensive studies to evaluate the potential effects of high altitude exposure on eyes following photorefractive keratectomy treatment for myopia[1]. Mader[1] examined individuals with radial keratotomy (RK), PRK, and untreated myopia exposed to 14,100 feet altitude for 3 days on Pikes Peak, Colorado.[4,5,] Refractive changes were seen in most subjects with RK, but not PRK or untreated myopia. The observed change in RK subjects were shown to be attributed to hypoxia rather than related to reduced atmospheric pressure.[2,-6] Follow-on Pikes Peak studies[3,6-9] found refractive and corneal changes in RK and early post-op Laser In-situ Keratomileusis (LASIK) subjects but not in PRK subjects. The Tanzer[8] study evaluated 30 naval aviators three months post-PRK treatment during a three hour simulated 17,500-foot altitude profile. All subjects were provided 100% oxygen during the flight profile. No significant changes were found in the group mean refraction, visual acuity or contrast acuity data.

These studies, however, did not thoroughly examine all potential hypobaric conditions an aircrew member might face. For example, the exposure duration at altitude of the Pikes Peak studies greatly exceeds a mission profile typical of military aircraft. The Tanzer study while simulating a real mission profile did not evaluate the potential effects of a rapid decompression or hypobaric conditions without supplemental (100%) oxygen support.

PURPOSE

This study was a prospective evaluation of high altitude exposure effects on visual acuity and contrast acuity, under high and low light conditions, before and after photorefractive PRK treatment. Two altitude chamber profiles were designed and accomplished to simulate conditions encountered by typical aircrew. One profile simulated a long duration flight mission that aircrew could expect to fly, namely unpressurized at 10,000-foot altitude, where supplemental oxygen is not required. The other profile examined a short exposure to simulate an actual operational mission and a rapid de-pressurization from an altitude of 35,000 feet.

SUBJECTS

Twenty non-smoking, non-flying active duty USAF personnel volunteered for the altitude study (16 males and 4 females). While representative of the active duty flying population in general, only myopic individuals as defined by the study protocol were selected and examined. Subjects were medically certified to undergo altitude exposure and completed an extensive baseline ophthalmic evaluation as part of the overall USAF PRK study. They also subsequently completed a standard USAF altitude chamber-training course to include an orientation exposure to 35,000-foot simulated altitude. Prior to each data collection profile all subjects were examined to determine their best visual acuity and, if required, were provided vision correction fabricated in a standard USAF issue aircrew spectacle frame (HGU-4/p). All subjects underwent PRK treatment at Wilford Hall Medical Center, Lackland AFB and served as their own pre- and post- PRK surgery control. Table 1 describes demographic characteristics of this subject population.

Age	Average: 33 years Range: 24-41	
Sex	16 males	4 Females
Refractive error (Spherical Equivalent)	Pre-PRK Treatment	-3.18 Diopters (-1.25 to –4.75)
	Post- PRK Treatment	-0.07 Diopters (+0.625 to -0.875)

Table 1. Subject Demographics

ALTITUDE CHAMBER PROFILES

EXPOSURE PROFILE #1 (10,000 ft simulated altitude - 12-hour exposure)

The AF Research Laboratory (AFRL) altitude chamber, Chamber "E" located on Brooks AFB, Texas was used for altitude exposures under this profile. Chamber E was sufficiently large to create a 20 ft "eye lane" optimizing data collection, in addition to providing space for six subjects, two clinical examiners, one inside observer (aerospace physiology officer or technician), and various data collection devices. The layouts of the chamber and test positions are shown in Figure 1. Exposure conditions are found in Table 2. The 10,000 foot altitude exposure was designed to simulate conditions found on a typical unpressurized C-130 special operations mission or a trans-oceanic flight maintaining cabin pressure (Air Force Instruction 11-206).

Figure 1: Chamber "E" Layout and Chart positioning

<table>
<tr><th colspan="4">STUDY PROFILE: 10,000 ft Altitude</th></tr>
<tr><th colspan="3">Altitude</th><th>Time tested</th></tr>
<tr><td colspan="3">Baseline: Ground (actual 675 feet)
Note: “ground level” is just above local altitude to ensure chamber seal</td><td>Day before exposure</td></tr>
<tr><td>Ear/Sinus Check</td><td colspan="2">Ground to 5,000 feet and return</td><td>20 minutes
prior to test condition</td></tr>
<tr><td>RUN 1</td><td rowspan="3">Test condition 1
10,000 feet – 12 hours</td><td rowspan="3">Test condition 2
Ground – 12 hours</td><td>2 – 4 hours at altitude</td></tr>
<tr><td>RUN 2</td><td>6 – 8 hours at altitude</td></tr>
<tr><td>RUN 3</td><td>10 – 12 hours at altitude</td></tr>
</table>

Table 2: Test Sequence for 10,000-foot Simulated Altitude Data Collection

The study protocol required two test conditions: 12 hour test cycle at ground level and a 12 hour test cycle at 10,000 feet. All subjects completed both conditions. Half of the subjects completed the ground condition prior to the altitude condition. The other half accomplished the altitude condition prior to the ground condition. Both conditions were accomplished in the same manner with test altitude being the only variable. To assure that all inside members had patent sinus and Eustachian passages, an “ear and sinus check” was accomplished prior to start of each altitude exposure. This check consisted of a brief exposure to altitude (5,000ft) and immediate return to ground level. Upon successful completion of this evaluation (no indications of trapped air conditions), one of the two altitude conditions was initiated: simulated altitude remaining at ground level or increased to 10,000 foot altitude at a climb rate of 5,000 ft/min. The chamber comfort conditions were maintained at approximately 72 degrees F and 14% humidity for exposure duration.

Visual performance data was collected at three intervals: approximately 2-4, 6-8, and 10-12 hours of continuous altitude exposure. Each data collection interval required approximately 1.5 hours to complete all tests on all subjects. Ambient air was maintained throughout the flight profile. When not active in data collection, subjects were allowed to talk, read, or watch video programs. Signs and symptoms of decompression sickness were monitored throughout the flight

by the chamber staff (inside and outside observers). Subjects were required to maintain alertness (not allowed to sleep) to enable self reporting of decompression symptoms. Any subjective hypoxic or decompression symptoms were immediately assessed by the inside observer. If any subject experienced a hypoxic event determined to be significant or indicative of decompression sickness (DCS), that member would be removed from the chamber for further evaluation. If they had minor subjective complaints, subjects were +given an option to breathe supplemental oxygen by mask. No subject developed significant hypoxia or DCS at any time during this study. About 1/2 of the subjects used the supplemental oxygen option at least once throughout the profile. None used supplemental oxygen more than 10 minutes during the flight profile.

The visual acuity data collection series consisted of five unique acuity charts (Figure 2) observed under either low or high illumination. Chamber E's standard florescence lighting provided the high illumination condition. The low illumination condition was accomplished using calibrated halogen light sources in place of the standard chamber lighting. Chart luminance was measured (Tektronix J6523) prior to and following each complete data collection run. Charts used and associated luminance levels are found in Table 3. Data collection was sequenced so that all subjects completed visual acuity testing under low illumination conditions prior to high illumination evaluation.

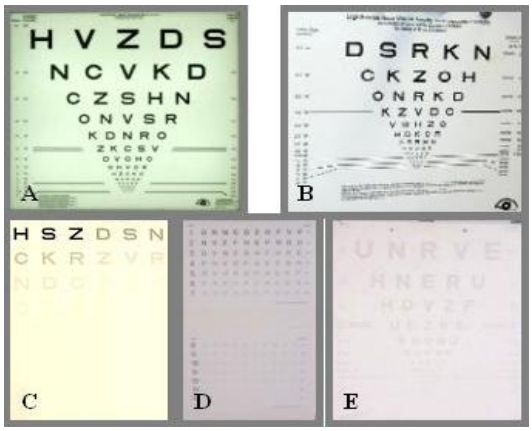


Figure 2: Visual Performance Charts

(A) ETDRS High Contrast – Distant Acuity, (B) ETDRS High-Contrast – Near Acuity, (C) Pelli-Robson Contrast Sensitivity, (D) Rabin Small Letter Low Contrast, (E) Bailey-Lovie – 10% Low Contrast

Illumination Measurements of Visual Acuity Charts		
CHART	**Luminance ("LIGHT") Cd/m^2**	**Luminance ("DARK") Cd/m^2**
ETDRS High Contrast	167	3.1
Bailey-Lovie 10% Contrast	152	0.62
Rabin Small Letter Contrast (SLCT)	181	3.8
Pelli-Robson	62	0.38
ETDRS Near	24	0.34

Table 3: Illumination Measurements of Visual Acuity Charts

ALTITUDE CHAMBER PROFILES

EXPOSURE PROFILE #1 (35,000 ft simulated altitude – 20 min exposure)

The AFRL altitude chamber, Chamber "C" located on Brooks AFB, Texas was used for all 35,000-foot simulated altitude exposures. This chamber provided sufficient space for 2 subjects, 1-2 clinical examiners, and various data collection devices. Additionally an inside observer was positioned in an attached emergency safety chamber, but was not exposed to simulated altitude unless required to provide emergency support for subjects and/or clinical examiners. There were no situations experienced during this study requiring emergency management. The layout of the chamber and test position is shown in Figure 3.

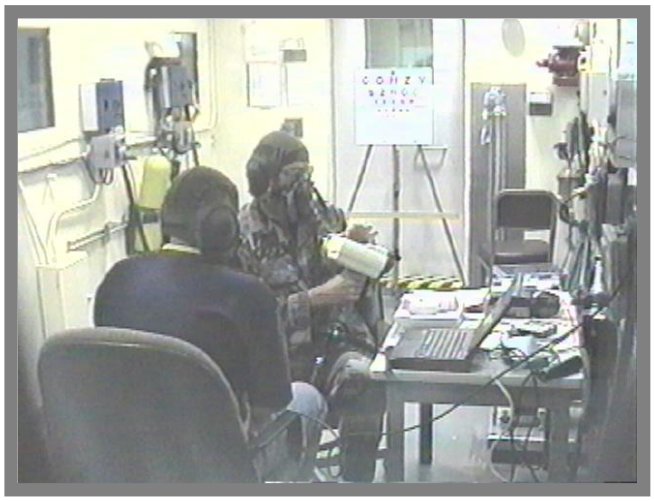


Figure 3: Chamber layout and Chart Positioning

Exposure conditions are found in Table 4. The 35,000-foot altitude condition was selected to simulate a high altitude profile, e.g. special operations mission and a rapid depressurization. To minimize potential decompression sickness risks, the study design limited the 35,000-foot altitude exposure to a maximum of 30 minutes. This time period reflected expected operational conditions and allowed sufficient, although limited, data collection. In an operational setting, an aircraft experiencing a sudden depressurization at 35,000-foot altitude will typically descend to a safer altitude within 30 minutes.

As described above in the 10,000-ft methods, an "ear and sinus check" was accomplished prior to the planned exposure profile. Following successful completion of the check, all subjects and inside examiners accomplished a two-hour 100% oxygen pre-breathe, a safety procedure to minimize decompression sickness risk. Upon completion of the pre-breathe period, subjects and inside examiners were transferred to Chamber "C." Subjects and examiners continued uninterrupted 100% oxygen support immediately following the pre-breathe procedure and throughout the data collection period. Following baseline (ground level) data collection, the chamber climbed at a rate of 5,000 ft/min. to an altitude of 35,000 ft.

Altitude Chamber Testing Sequence

35K Exposure

Ground	Ground 675 feet; 742 mm Hg	2 hours before exposure
RUN 1	35,000 feet	5 – 30 minutes at altitude
RUN 2	Ground (675 feet)	5 – 30 minutes after descent

Table 4: Testing Profile for 35,000-foot Simulated Altitude Data Collection

OCULAR PERFORMANCE

The visual performance of the 35,000-foot simulated altitude data collection series was measured using an ETDRS high contrast visual acuity chart (figure 4) set at a calibrated 3 meter distance from the subject. This chart was fixed in position throughout all testing. Monocular visual acuity data was collected on each data collection interval under low and high illumination.

Standard chamber lighting provided high illumination. Indirect lighting outside of the chamber was used in place of standard chamber lighting to create a controlled low light chart illumination. Chart luminance was calibrated prior to each altitude profile. Subjects completed chart data collection first under low illumination and then under high illumination.

Figure 4: ETDRS HIGH CONTRAST VISUAL ACUITY TEST

Refractive and corneal contour measures were captured using other standard instruments. Corneal topography data was acquired with EyeSys Vista™ HANDHELD CORNEAL TOPOGRAPHER (Figure 5). The topography unit had the following features:

Working Distance:	12.5mm
Field of View:	10mm X 14mm
Corneal Coverage:	0.9mm to 9.0mm
Measurement Area Center:	3.2mm (R8mm)
Resolution:	0.10 Diopters (D)
Reproducibility:	±0.20 D

Figure 5: EyeSys Vista™ HANDHELD CORNEAL TOPOGRAPHER

Two corneal topography measures of each eye were accomplished approximately within 30 seconds of each other at each data interval. The corneal topography data was captured and then transferred onto a laptop computer, processed using EyeSys software and later printed to hardcopy. Specific data measures were subsequently transferred to a central database for statistical analysis.

Auto-Refraction and Auto-Keratometry data were simultaneously acquired using a RETINOMAX K-PLUS AUTO REFRACT-KERATOMETER (Figure 6). The Retinomax K-Plus had the following features:

Multiple Fast refractive/Keratometric readings:	0.15 – 0.25 seconds/reading
Keratometric range:	30.62 – 67.5 Diopters (D)
Refractive range:	-18D to +23D (S+C)/± 12D
	Axis: 1° to 180°

Figure 6: RETINOMAX K-PLUS AUTO REFRACT-KERATOMETER

Two sets of refractive and keratometric readings were captured on each eye at each data collection interval. Each set of readings was printed to hardcopy format and subsequently transferred into a central database for statistical analysis.

ANALYSIS

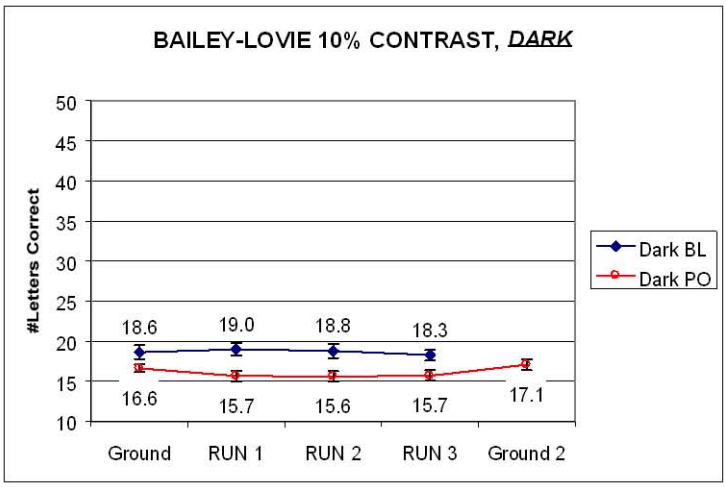
The refractive measures were analyzed by standard refractive error analysis utilizing standard spherical equivalent techniques (sum of spherical and ½ of the cylinder powers.) Statistical Analysis included: descriptive statistics; Within Subject Contrasts - multivariate tests (Pillai's Trace, Wilks' Lambda, Hotelling's Trace, Roy's Largest Root), Mauchly's Test of Sphericity; Between Subjects Effects - Sum of Squares.

RESULTS

10K ALTITUDE: VISUAL PERFORMANCE: Bailey-Lovie Chart

Bailey-Lovie Charts are designed as low contrast (10% target to background contrast) acuity measures. Figure 8 graphically presents the mean low contrast acuity performance of the altitude subjects under low light conditions. No statistical significant change was found in visual performance on Bailey-Lovie visual acuity charts either between ground level and altitude or at any of the altitude intervals. There was a notable, but insignificant difference between the mean subject responses, pre-treatment versus post-treatment. The number of correctly-read letters was slightly less following PRK treatment. Figure 7's adjoining table reports the number of eyes that gained or lost more than four or nine letters. Greater than four letters is equivalent to one line of acuity loss. Greater than nine letters is equivalent to two lines of acuity loss. Although mean acuity performance overall was not significantly different, approximately half of the subjects lost and half gained one line of acuity from pre-altitude measure at the first altitude measure before PRK treatment. This trend persisted throughout the pre-treatment data runs. In contrast, twice as many subjects lost a line of acuity as those who gained, post-operatively.

Under high light conditions, performances on the Bailey-Lovie chart were significantly better overall than under low light conditions (Figure 8). Subjects did not have significant difference in performance under this condition pre- or post-treatment. However, similar to the low light conditions, individuals performed better overall pre-treatment than post-treatment.



Pre-op	R1	R2	R3	G2
%Lost>4	10	17.5	17.5	
%Lost>9	2.5	0	0	
%Gained>4	20	20	15	
%Gained>9	0	5	0	

Post-op	R1	R2	R3	G2
%Lost>4	20	15	15	10
%Lost>9	0	0	0	0
%Gained>4	10	5	7.5	15
%Gained>9	0	0	0	0

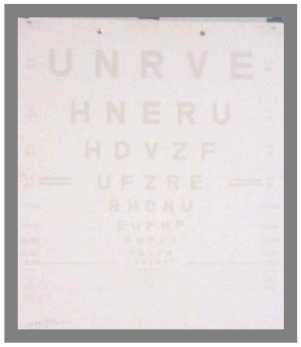
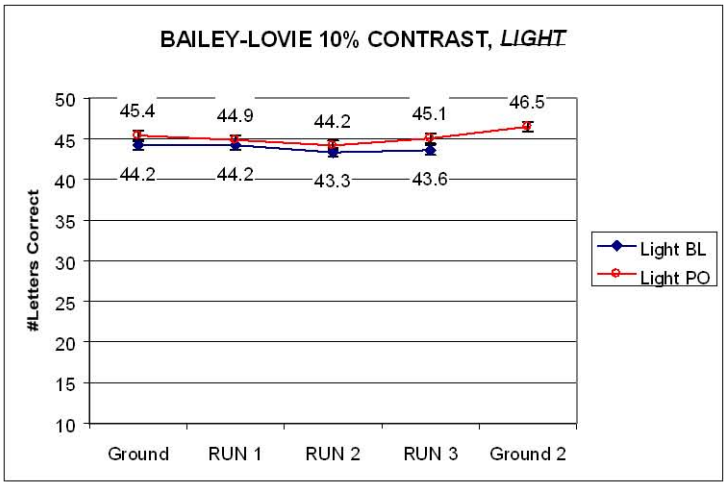


Figure 7: Bailey-Lovie: data collected under low light conditions



Pre-op	R1	R2	R3	G2
%Lost>4	7.5	12.5	15	
%Lost>9	0	2.5	0	
%Gained>4	10	2.5	5	
%Gained>9	0	0	0	

Post-op	R1	R2	R3	G2
%Lost>4	10	22.5	7.5	5
%Lost>9	0	0	0	0
%Gained>4	5	5	7.5	5
%Gained>9	0	0	0	0

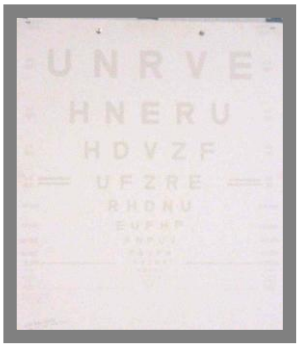
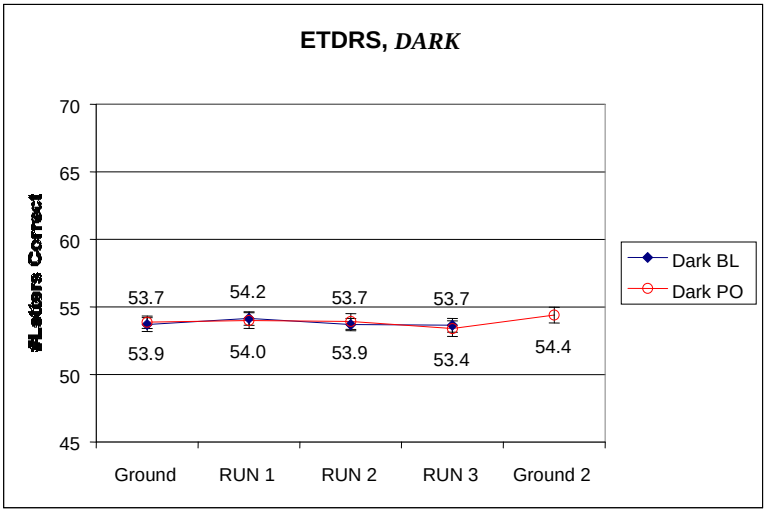


Figure 8: Bailey-Lovie: data collected under high light conditions.

10K ALTITUDE - VISUAL PERFORMANCE: ETDRS High Contrast Distant Chart

ETDRS charts used were designed as high contrast acuity measures. Figure 9 graphically presents the mean acuity performance of the altitude subjects under low light conditions. No statistical change was found in visual performance either between ground level and altitude or at any of the altitude intervals. There was a notable but insignificant difference between the mean subject responses, pre-treatment versus post-treatment. The number of correctly read letters was slightly less following PRK treatment. Figure 9's adjoining table reports the number of eyes that gained or lost more than four or nine letters. Greater than four letters is equivalent to one line of acuity loss. Greater than nine letters is equivalent to two lines of acuity loss. Although mean acuity performance overall was not significantly different, approximately half of the subjects lost and half gained one line of acuity at the first altitude measure before PRK treatment. This trend persisted throughout the pre-treatment data runs. In contrast, twice as many eyes lost a line of acuity as those who gained, post-operatively.

Under high light conditions, performances on the ETDRS chart were significantly better overall than under low light conditions (Figure 10). Subjects did not have significant differences in performance under this condition pre- or post-treatment. However, as opposed to the lowlight conditions, there was a statistical reduction in mean acuity performance post-treatment at the first altitude data point.



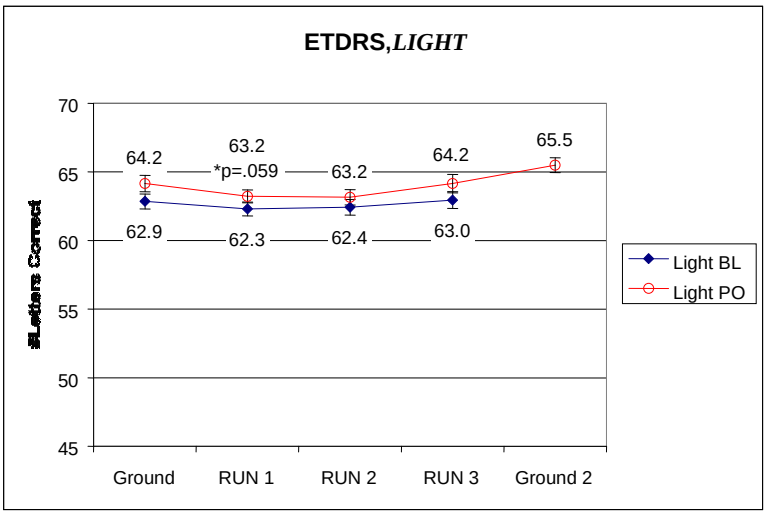
Pre-op

	R1	R2	R3	G2
%Lost>4	5	2.5	7.5	
%Lost>9	0	0	0	
%Gained>4	2.5	5	7.5	
%Gained>9	0	0	0	

Post-op

	R1	R2	R3	G2
%Lost>4	10	10	12.5	10
%Lost>9	0	2.5	0	0
%Gained>4	10	7.5	5	12.5
%Gained>9	0	0	0	2.5

Figure 9: ETDRS High Contrast: data collected under low light conditions



Pre-op

	R1	R2	R3	G2
%Lost>4	5	5	5	
%Lost>9	0	0	0	
%Gained>4	2.5	2.5	7.5	
%Gained>9	0	2.5	0	

Post-op

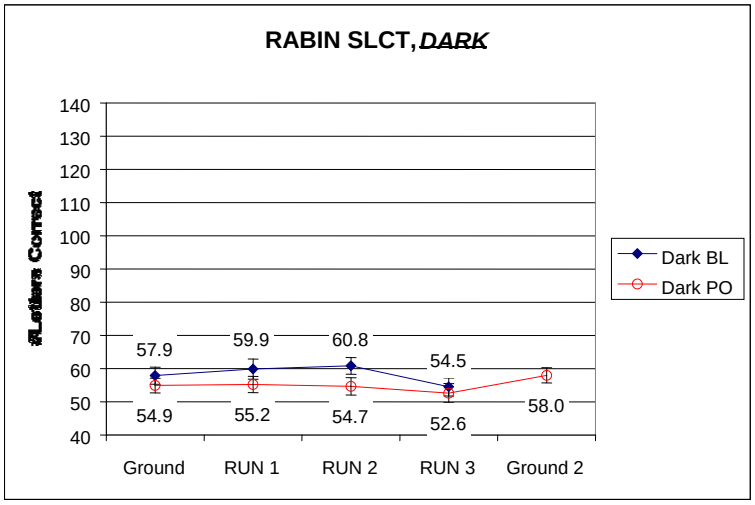
	R1	R2	R3	G2
%Lost>4	7.5	12.5	0	2.5
%Lost>9	0	0	0	0
%Gained>4	0	2.5	7.5	17.5
%Gained>9	0	0	0	0

Figure 10: ETDRS High Contrast: data collected under high light conditions

10K ALTITUDE -VISUAL PERFORMANCE: RABIN Small Letter Low Contrast Chart

Rabin Small Letter Low Contrast Charts were designed as low contrast, but fixed visual acuity measures. All targets are of equal acuity demand, approximately 20/25. Figure 11 graphically presents the mean contrast performance of the altitude subjects under low light conditions. No statistical change was found in visual performance neither between ground level and altitude nor between any of the altitude intervals. Figure 11's adjoining table reports the number of eyes that gained or lost more than nine or nineteen letters. Greater than nine letters is equivalent to one line of contrast loss. Greater than nineteen letters is equivalent to two lines of contrast loss. Mean contrast performance overall was not significantly different. Individually, similar numbers of subjects lost or gained one line of contrast comparing pre- and post-treatment data. This chart demonstrated a high level of variability.

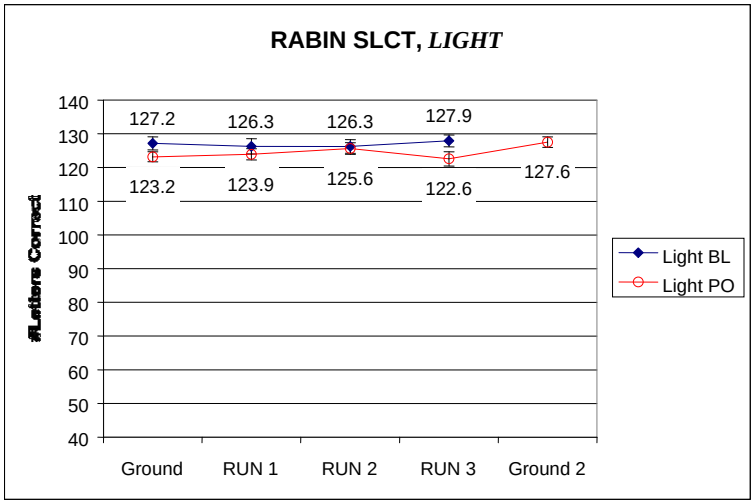
Under high light conditions, performances on the RABIN chart were significantly better overall than under low light conditions (Figure 12). Subjects did not have significant difference in performance under this condition pre- or post-treatment.



Pre-op	R1	R2	R3	G2
%Lost>9	15	15	20	
%Lost>19	5	0	5	
%Gained>9	30	25	7.5	
%Gained>19	7.5	15	2.5	

Post-op	R1	R2	R3	G2
%Lost>9	25	17.5	20	12.5
%Lost>19	7.5	12.5	12.5	7.5
%Gained>9	25	22.5	10	27.5
%Gained>19	7.5	2.5	2.5	12.5

Figure 11: RABIN small letter low contrast: data collected under low light conditions



Pre-op	R1	R2	R3	G2
%Lost>9	12.5	7.5	7.5	
%Lost>19	5	5	5	
%Gained>9	5	10	7.5	
%Gained>19	2.5	2.5	2.5	

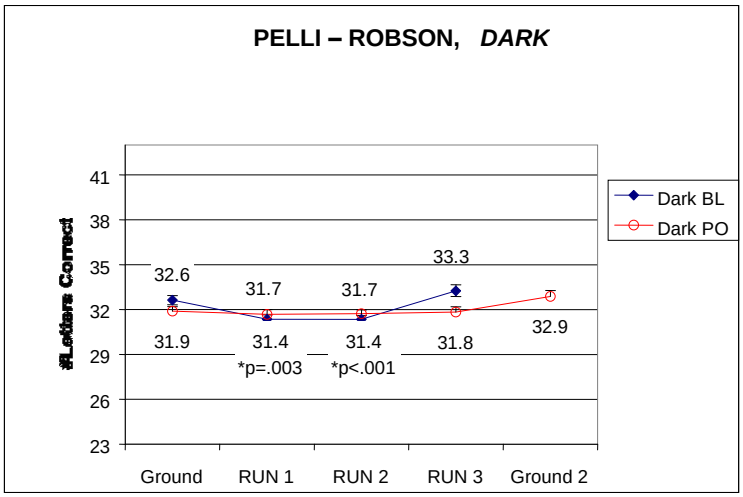
Post-op	R1	R2	R3	G2
%Lost>9	7.5	10	10	5
%Lost>19	0	0	7.5	0
%Gained>9	7.5	15	7.5	30
%Gained>19	2.5	0	0	2.5

Figure 12: RABIN small letter low contrast: data collected under high light conditions

10,000 FT ALTITUDE - VISUAL PERFORMANCE: Pelli-Robson Contrast Chart

Pelli-Robson Contrast Charts were designed as variable contrast, but fixed visual acuity demand measures. Figure 13 graphically presents the mean contrast performance of the altitude subjects under low light conditions. No statistical change was found in visual performance neither between ground level and altitude nor at any of the altitude intervals post-treatment. However, there was a significant mean subject response difference observed between ground level and two altitude measures pre-treatment. Figure 13's adjoining table reports the number of eyes that gained or lost more than two or five letters. Greater than two letters is equivalent to one interval of contrast loss. Greater than five letters is equivalent to two intervals of contrast loss. Significantly more eyes demonstrated reduce contrast performance prior to than after PRK treatment.

Under high light conditions, performances on the Pelli-Robson chart were similar to the low light condition (Figure 14). Pre-treatment, subjects' performance was reduced at altitude. Post-treatment, subjects did not have significant difference in performance under this condition.



Pre-op

	R1	R2	R3	G2
%Lost>2	27.5	30	10	
%Lost>5	0	0	0	
%Gained>2	2.5	0	25	
%Gained>5	0	0	5	

Post-op

	R1	R2	R3	G2
%Lost>2	10	10	10	2.5
%Lost>5	2.5	2.5	2.5	2.5
%Gained>2	7.5	7.5	15	20
%Gained>5	0	0	2.5	5

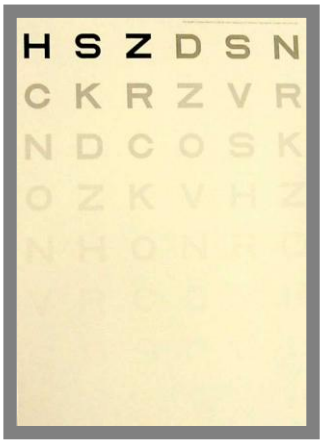
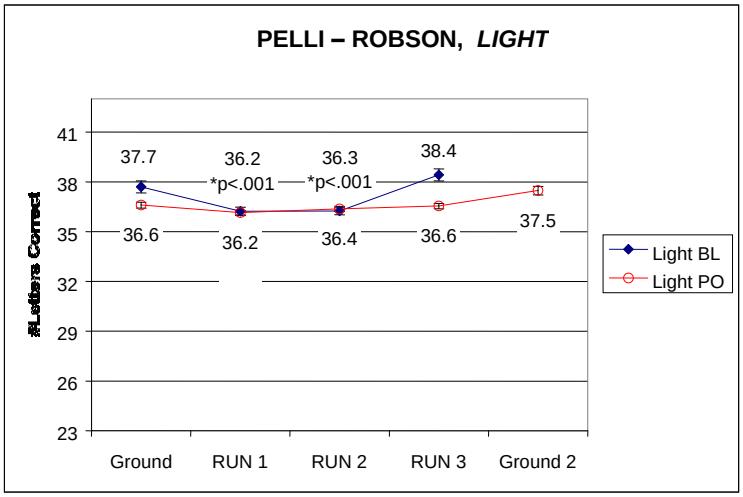


Figure 13: Pelli-Robson Contrast Chart: data collected under low light conditions



Pre-op

	R1	R2	R3	G2
%Lost>2	37.5	32.5	7.5	
%Lost>5	2.5	2.5	0	
%Gained>2	2.5	0	12.5	
%Gained>5	0	0	0	

Post-op

	R1	R2	R3	G2
%Lost>2	7.5	5	5	2.5
%Lost>5	0	0	0	0
%Gained>2	2.5	0	0	15
%Gained>5	0	0	0	0

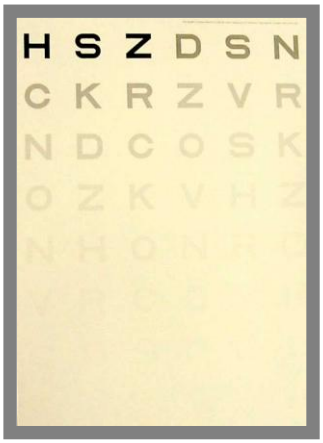


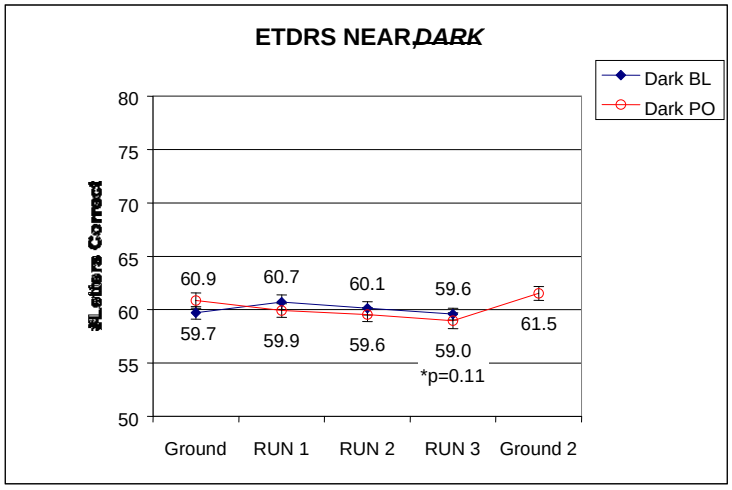
Figure 14: Pelli-Robson Contrast Chart: data collected under high light conditions

10,000 FT ALTITUDE - VISUAL PERFORMANCE: ETDRS High Contrast Near Chart

ETDRS High Contrast Near Charts are designed as acuity measures. Figure 15 graphically presents the mean acuity performance of the altitude subjects under low light conditions. No statistical change was found in visual performance neither between ground level and altitude nor at any of the altitude intervals post-treatment. However, there was a significant mean subject response difference observed between ground level and the last altitude measures pre-treatment, not observed post-treatment. Figure 16's adjoining table reports the number of eyes that gained or lost more than four or nine letters. Greater than four letters is equivalent to one line of acuity loss. Greater than nine letters is equivalent to two lines of acuity loss. More eyes demonstrated loss of one line of acuity post-treatment as compared to those pre-treatment.

Under high light conditions, performances on the Pelli-Robson chart were similar to the low light condition (Figure 16). No statistical change was found in visual performance neither between ground level and altitude nor at any of the altitude intervals post-treatment.

However, there was a significant mean subject response difference observed between ground level and the last altitude measures pre-treatment, not observed post-treatment.



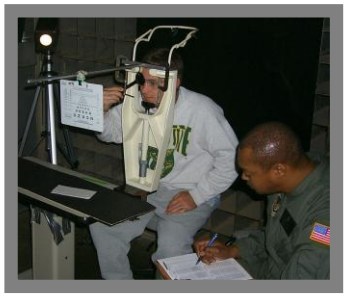


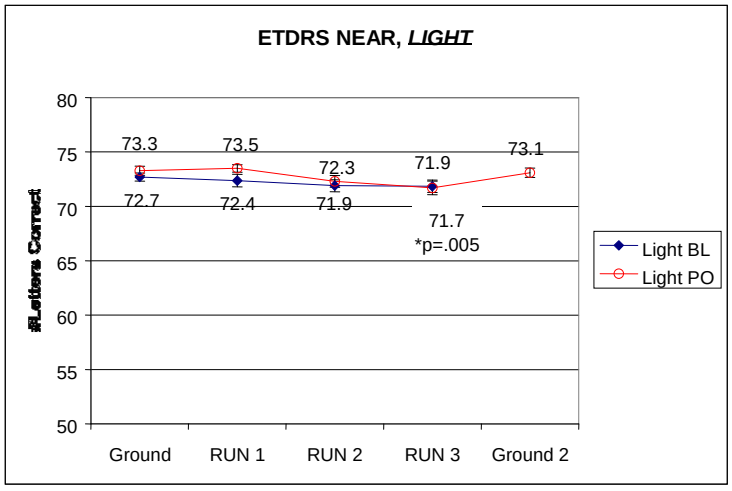
Figure 15: ETDRS High Contrast Near Chart: data collected under low light conditions

Pre-op

	R1	R2	R3	G2
%Lost>4	7.5	7.5	17.5	
%Lost>9	0	0	0	
%Gained>4	12.5	10	7.5	
%Gained>9	0	2.5	0	

Post-op

	R1	R2	R3	G2
%Lost>4	17.5	20	22.5	7.5
%Lost>9	0	0	2.5	0
%Gained>4	2.5	5	0	17.5
%Gained>9	0	0	0	0



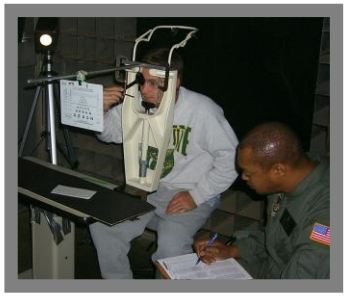


Figure 16: ETDRS High Contrast Near Chart: data collected under high light conditions

Pre-op

	R1	R2	R3	G2
%Lost>4	15	10	7.5	
%Lost>9	0	2.5	2.5	
%Gained>4	5	2.5	0	
%Gained>9	0	0	0	

Post-op

	R1	R2	R3	G2
%Lost>4	0	15	17.5	5
%Lost>9	0	0	2.5	0
%Gained>4	2.5	0	0	5
%Gained>9	0	0	0	0

35,000 FT ALTITUDE - VISUAL PERFORMANCE: ETDRS High Contrast Chart

ETDRS charts used were designed as high contrast acuity measures. Figure 17 graphically presents the mean acuity performance of the altitude subjects under low light conditions. No statistical change was found in visual performance between altitude and ground level measures. There was no statistical change between pre-flight and post-flight measures.

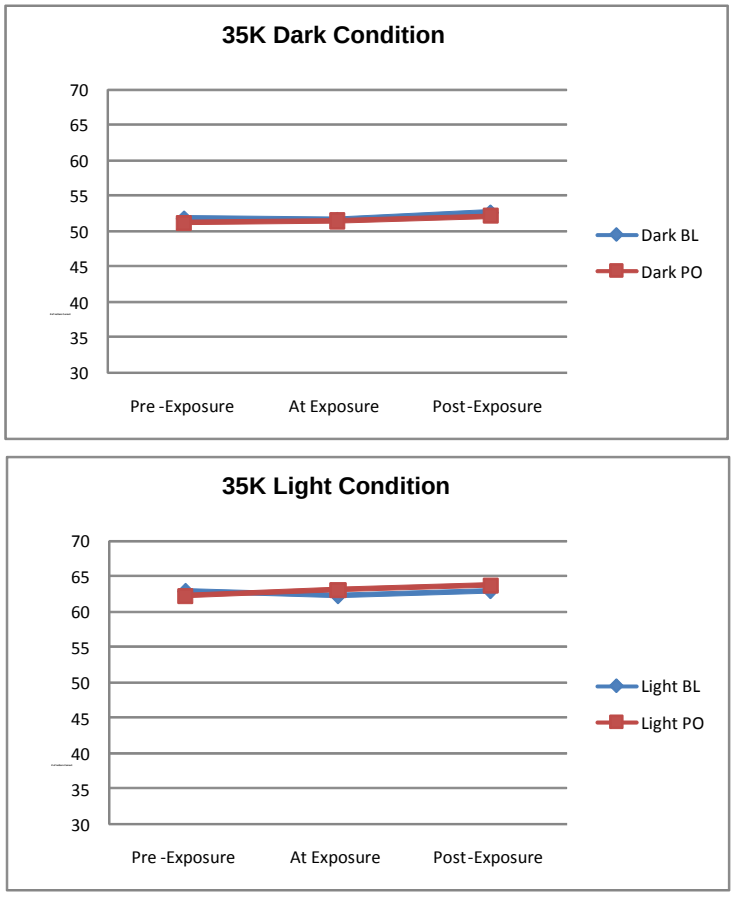
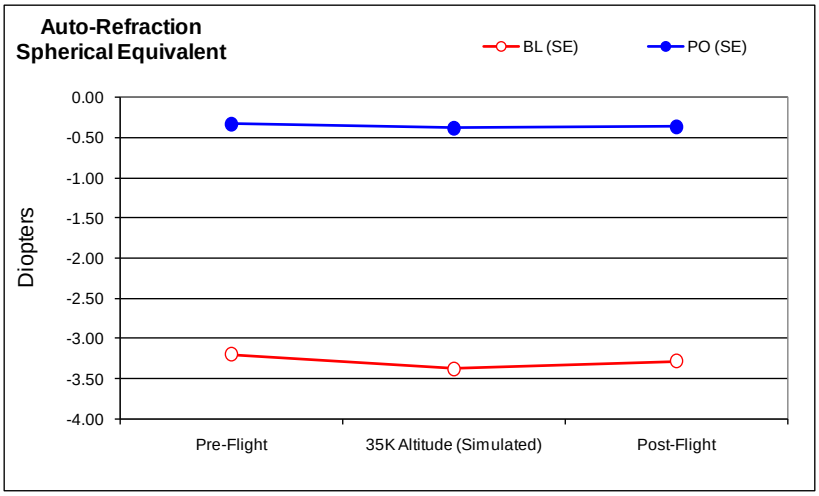


Figure 17: ETDRS High Contrast: data collected under low light conditions

35,000 FT ALTITUDE – Refractive Error/Keratometric Changes

The Retinomax instrument simultaneously measures refractive error and primary meridional keratometric measures. Figure 18 graphically presents the mean refractive error and mean keratometric measurement of the altitude subjects measured before, during, and after altitude exposure. No statistical change was found in either measure between altitude and ground level measures. There was no statistical change between pre-flight and post-flight measures



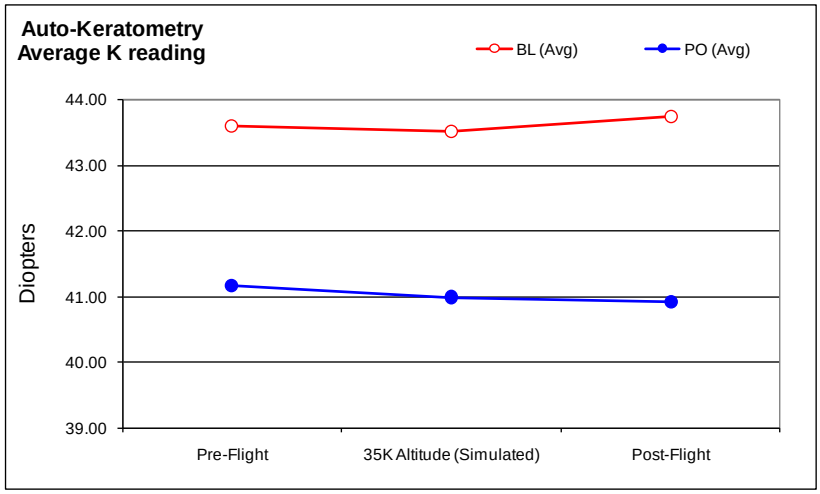


Figure 18: Auto-Refraction and Auto-Keratometry

DISCUSSION

During the chamber rides prior to PRK surgery, the Pelli-Robson chart LIGHT and DARK ($p<.001$) and Rabin SLCT DARK ($p=.02$) showed a change in mean acuity for the 40 eyes. Post-hoc analysis (*Bonferroni) showed a decrease in Pelli-Robson acuity of about 1.5 to 2 letters between Ground and RUNs 1 and 2, under DARK and LIGHT illumination (Figure 1). There was a decrease in Rabin SLCT acuity of about 4 letters between RUNS 3 and 4 (Figure 2), but not between Ground level. This is consistent with previous PRK studies observing slight reduction in visual performance at altitude (10,000 feet) without supplemental oxygen.

During the chamber rides after PRK surgery, there was a main effect of time at altitude for the ETDRS near chart in DARK ($p=0.019$) and LIGHT ($p=.001$); the Rabin SLCT in LIGHT ($p=.013$); and the ETDRS chart in LIGHT ($p=0.030$). Post-hoc analysis showed a decrease in ETDRS near acuity of about 2 letters between Ground and RUN 3 for the DARK and LIGHT illumination (Figure 4). There was a 1 letter change for ETDRS LIGHT for RUN 1. Although there were reliable changes in acuity for the Rabin SLCT chart in LIGHT, the differences were not significantly different from Ground level. As observed in pre-PRK surgery data collection, visual performance was slightly reduced at altitude (without supplemental oxygen) compared to ground level. The impact of time at altitude was similar for both pre- and post- PRK surgery. Therefore, human corneas response to altitude was unchanged by PRK treatment in the context of this study.

The Repeated Measures ANOVA included data for Ground through RUN 3. These data examined the effect of altitude exposure over time. To gather a sense of persistence of, or delayed effect of altitude exposure, data from the "Ground 2" tests (the day following altitude exposure - only accomplished in post-PRK surgery) are included in Figures 1 – 6 for illustrative purposes. In all subjects there was no significant change in visual performance persisting after exposure. In individuals in whom a mild decrease of acuity occurred at altitude, there was full recovery seen the following day at Ground level.

These results are consistent with those of Tanzer, et al [3, 5] in studies at altitude on Pikes Peak. The Pikes Peak study, conducted over a three days at 14,100 feet, reported no significant change in PRK and LASIK treated subjects as opposed to significant change in RK treated subjects. That study exceeded mission profiles of typical military aircraft. Further above 10,000

feet, current Air Force policy requires use of supplemental oxygen. Subjects in our study did not use supplemental oxygen throughout the 10,000 foot exposure dataset as would be required for military operations, rather only when subjectively requested. Pre- and Post- PRK data collected at 35,000 feet while using supplemental oxygen, did not reveal significant visual performance, corneal shape, or refractive error change. Consistent with other PRK altitude studies, this suggests that no significant effect on treated or untreated PRK corneas were induced by reduced atmospheric pressure over the experimental conditions of this study [2].

CONCLUSION

Subjects treated with standard photorefractive keratectomy (PRK) were found to have no significant change in their visual performance at 10,000 feet (no supplemental oxygen), nor at 35,000 feet (highest operational military cabin altitude; with supplemental oxygen) over the experimental condition of this study. Consequently, within the design limits of this study, PRK, as a surgical treatment for myopic eyes, appears safe and compatible with routine aviation altitude profiles without risk for transient or permanent visual effects that would potentially impact operational performance or short term ocular health. Additional studies, however, are required to assess the longer term consequences and the potential effects of more prolonged exposure times at altitudes at or below 10,000 feet (as might be associated with sustained operations at higher terrain elevations) that would not typically be associated with supplemental oxygen.

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